



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

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Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
Tel 781.279.1675 Fax 781.279.1742

WARNING LETTER

NWE-16-98W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

July 7, 1998

Ms. Charlotte G. Henderson
President
Dermaron Corp.
15 Hale Street
Haverhill, Massachusetts 01830

Dear Ms. Henderson:

This letter concerns your firm's marketing of **WORK SHIELD Poison Ivy & Oak Skin Protectant and Cleansing Cream**, **WORK SHIELD Factory Formula Skin Cream**, and **WORK SHIELD Under Glove Skin Cream** for over-the-counter (OTC) human drug use as described below. During inspections of your establishment by the U.S. Food and Drug Administration (FDA) on October 18 and November 12, 1996 and on January 17, 1997, samples of these products and their accompanying promotional labeling, which includes brochures and fliers, were collected.

Based on the information obtained during FDA's inspections of your firm and as represented in their respective labeling, **WORK SHIELD Poison Ivy & Oak Skin**

Protectant and Cleansing Cream, **WORK SHIELD Factory Formula Skin Cream**, and **WORK SHIELD Under Glove Skin Cream** are intended to form a prophylactic barrier on the skin to provide protection against diseases, including contact dermatitis and acute toxic reactions, caused by exposure to poison ivy and poison oak, to multiple chemicals and industrial compounds, and to various protective glove materials (e.g., latex). The labeling also claims that the effectiveness of these products is not adversely affected by frequent hand washing. With regard to these intended prophylactic skin barrier uses, we note the prominence of the term **SHIELD** and other representations and suggestions in the labeling, such as:

WORK SHIELD Poison Ivy & Oak Skin Protectant and Cleansing Cream

“...Use Before Exposure To Poison Ivy & Oak Plants... available to... children and adults allergic to these poisonous plants... STOP THE ITCH BEFORE IT STARTS... the dried cream forms many micro-layers... that carry away plant oils when washed. New fresh layers... are exposed. Washing can be repeated when necessary. One application usually lasts throughout the day... The cream must be applied to clean dry skin prior to exposure...”

WORK SHIELD Factory Formula Skin Cream

“...Use WORK SHIELD before working with... Cutting Oils... Cold [sic] Tar... Lacquers... Grease... Solvents... Diesel Oil... Fiberglass... Animal glues... Detergents... Waxes... Wetting agents carry away... cutting oil, carbon, glue, lacquers, diesel oil and inks exposing refreshed new base layers of cream... Lasts throughout repeated washings... One WORK SHIELD application usually lasts throughout the work shift... reddened skin caused

by working conditions requires immediate attention..."

WORK SHIELD Under Glove Skin Cream

"...the continuous use of gloves can cause dry reddened skin... Use WORK SHIELD before wearing gloves made from... Latex... Vinyl... Nitril [sic]... Polyethylene... Neoprene... Butyl... forms many micro layers... Repeated washing exposes fresh cream layers, ready for additional work... One application of Under Glove WORK SHIELD usually lasts at least four hours..."

We also note that the promotional labeling accompanying all of the **WORK SHIELD** products marketed by your firm, and the immediate container label for **WORK SHIELD Factory Formula Skin Cream**, include the statement "First Since 1987." Since Dermaron was not in operation at that time, we regard this statement to refer to the product [REDACTED], which had been marketed by [REDACTED] as a prophylactic skin "barrier" or "shield" to prevent diseases caused by exposure to multiple chemicals and industrial compounds. We note further that all of the **WORK SHIELD** products marketed by your firm (i.e., **WORK SHIELD Poison Ivy & Oak Skin Protectant and Cleansing Cream**, **WORK SHIELD Factory Formula Skin Cream**, and **WORK SHIELD Under Glove Skin Cream**) are remarkably similar in formulation, color, odor, consistency, packaging, labeling, and promotion to three products that were marketed by [REDACTED] namely [REDACTED] respectively. For your information, in 1990 FDA classified all three of these [REDACTED] products as unapproved "new drugs," and notified [REDACTED] of these and other related violations of the Federal Food, Drug, and Cosmetic Act (FFDCA) associated with the marketing of those products.

Based on their intended uses described above, **WORK SHIELD Poison Ivy & Oak Skin**

Protectant and Cleansing Cream, WORK SHIELD Factory Formula Skin Cream, and WORK SHIELD Under Glove Skin Cream are "drugs" as specified in section 201(g) of the FFDCA, and none of these products is subject to FDA's OTC Drug Review. Since we are not aware of any substantial scientific evidence that these products are generally recognized by scientific experts as safe and effective for the labeled indications described above, they are "new drugs" under section 201(p) of the FFDCA. "New drugs" may not be legally marketed in the United States without an approved new drug application (NDA) required under section 505(a) of the FFDCA. We note that none of the **WORK SHIELD** products marketed by your firm is covered by an FDA-approved NDA. In addition, these products are also misbranded under section 502(f)(1) of the FFDCA, because they do not bear adequate directions for their safe and effective use for the purposes noted above.

This letter is not intended to be a comprehensive review of the above named products or any other products marketed by your firm. It is your responsibility to assure that all requirements of the FFDCA and all pertinent regulations are being met. You should take prompt action to correct these violations. Federal agencies are routinely advised of the issuance of Warning Letters so that they may take this information into account when considering the award of government contracts.

We request that you reply within fifteen working (15) days of your receipt of this letter stating the action you will take to correct the violations described above. Failure to promptly correct these violations may result in enforcement action being initiated without further notice. The FFDCA provides for seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products under sections 304 and 302, respectively.

You may direct your reply to Mark Lookabaugh, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Mr. Lookabaugh

at 781.279.1675 ext. 118.

Sincerely,



John R. Marzilli
District Director

